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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,638	12/14/2000	Olivier De La Charriere	016800-429	6191

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Norman H. Stepno
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/735,638

Applicant(s)
De Lacharriere

Examiner
Gollamudi S. Kishore, Ph.D

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 5, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-114 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

The request for the extension of time, amendment and terminal disclaimers dated 11-5-01 are acknowledged.

Claims included in the prosecution are 25-51, 53-81, 83-11 and 113-114.

Double Patenting

In view of the terminal disclaimers, the double patenting rejections have been withdrawn.

Claim Rejections - 35 U.S.C. § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 25-28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 112 and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/14084.**

WO teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions

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are in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant while admitting that WO discloses the use of a substance P antagonist as a medicinal and further prophetically discloses that such antagonists may be administered by topical application, argue that WO does not disclose or fairly suggest a method treating sensitive skin which comprises topically applying to said sensitive skin an effective amount of at least one substance P antagonist containing composition, wherein said effective amount of said at least one substance P antagonist is formulated into a topically applicable cosmetically or dermatologically-acceptable medium therefor. This argument is not found to be persuasive. Instant claims recite the topical administration of only the substance P antagonist (without the presence in the composition of the irritant which causes the release of the substance P) for the treatment of the conditions such as skin irritation and pruritus; WO teaches P antagonist in a topical formulation such as ointments, creams, lotions for the treatment of same skin conditions; the very fact that the person got pruritus or irritation of the skin indicates that the skin of the person was sensitive and therefore, the reference meets the requirements of instant claims (see also *In re Woodruff*, (CAFC), 16 USPQ2nd. 1934). With regard to applicant's arguments that the examiner did not give sufficient weight to the fact that the claims require a specific

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combination which is comprised in specific relative ratios (amounts effective to treat sensitive skin or capsaicin sensitive skin) which is not suggested by the reference, the examiner points out that none of the claims except claims 32-33, 62-63, 92-93 recite the specific amounts of substance P antagonists and said claims which recite the percentages, recite the ranges as low as 0.00001 or 0.000001 % and applicant has not shown that the reference does not teach such amounts. With regard to applicant's arguments that WO does not disclose active ingredients such as proteins, vitamins etc., the examiner points out that the rejection does not include those claims.

Claim Rejections - 35 U.S.C. § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 25-28, 32-34, 45-46, 51-52, 55-58, 62-64, 75-76, 85-88, 97, 101, 105-106, 111, 112 and 114 are rejected under 35 U.S.C. § 103 as being unpatentable over WO 93/14084.

As pointed out above, this publication teaches a method of treatment of skin by the topical application of the claimed P antagonists for the treatment of diseases such as pruritus and urticaria. The compositions can be in the form of ointments, creams, lotions and various other forms and contain other additives and therapeutic agents. (note the abstract, page 5, lines 19-20, pages 13-14 and claims). WO does not provide any specific examples for the topical application to the sensitive skin. However, based on the teachings

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of WO it would have been obvious to one of ordinary skill in the art to use the substance P antagonists taught by WO to counter the irritant side effects of a substance in the cosmetic composition due to the release of substance P since the antagonists counter the substance P.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant provides no specific arguments to the 103 rejection. The combined arguments (for 102 and 103) have already been addressed above. With regard to applicant's specific argument that WO does not teach the coadministration of irritants as recited in claims 47-50, 77-80 and 107-110, the examiner points out that these claims recite substances such as proteins, protein hydrolysates and tocopherol as the active agents and not as irritants. It is within the skill of the art to include additional active agents expecting at least an additive effect.

6. Claims 25-114 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallengren (contact Dermatitis), Wallengren (BR. J. Dematitis) in combination with WO 83/01252 and/or WO 93/14084 (all are of record).

Wallengren (Contact dermatitis) teaches that the substance P antagonist Spantide diminishes the contact dermatitis caused by nickel sulfate (note the abstract and page 351).

Similarly, Wallengren (Br. J) teaches the inhibiting effect of substance P antagonists against various irritants (note the entire article).

The WO publications each teach the use of substance P antagonists in medicinal preparations including topical formulations (note the entire publications).

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It would thus, be obvious to one of ordinary skill in the art to prepare compositions containing substance P to combat the irritations caused by certain agents, particularly in view of the WO publications which show the use of these substances in the medicinal preparations.

Applicant's arguments have been fully considered, but are not found to be persuasive. The essence of applicant's arguments appear to be that Wallengren (Contact dermatitis; Br. J) discloses separately administering a substance P antagonist and the potential irritant wherein the irritant is administered either topically or via injection. This argument is not found to be persuasive since instant claim do not recite the requirement of the presence of the irritant in the same composition. As pointed out above, instant claims recite the topical administration of only the substance P antagonist (without the presence in the composition of the irritant which causes the release of the substance P). With regard to the claims which recite additional agents such as proteins and protein. hydrolysates, the examiner points out that the claims recite them as additional 'active agents' and not as irritants. With regard to WO 93 and WO 83 applicant once again while acknowledging that these references teach the topical application of substance P antagonists argue that they do not teach treating sensitive/capsaicin sensitive skin or preventing irritation of otherwise irritant compounds. This argument has been addressed above. In summary, the examiner points out that the references clearly teach that the substance antagonists act against the substance P released which causes the irritation and this antagonist effect will

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be the same whether the substance P is released in a sensitive skin or non-sensitive skin.

The rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

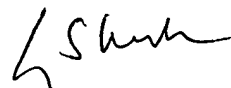
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

January 10, 2002